UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36593

SOLENO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0523891**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

203 Redwood Shores Parkway, Suite 500,
Redwood City, California
(Address of principal executive offices)

94065
(Zip Code)

(650) 213-8444
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SLNO	NASDAQ
Common Stock, $0.001 per value, underlying the warrants	SLNOW	NASDAQ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 1, 2019, there were 44,658,054 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

SOLENO THERAPEUTICS, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	September 30, 2019	December 31, 2018
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 11,225	$ 23,099
Prepaid expenses and other current assets	375	529
Due from related party	9	64
Minority interest investment in former subsidiary	—	978
Total current assets	11,609	24,670
Long-term assets		
Property and equipment, net	46	12
Intangible assets, net	17,011	18,469
Other long-term assets	59	—
Total assets	$ 28,725	$ 43,151
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,735	$ 934
Accrued compensation and other current liabilities	1,719	943
Total current liabilities	3,454	1,877
Long-term liabilities		
Series A warrant liability	25	49
2017 PIPE Warrant liability	3,667	4,563
2018 PIPE Warrant liability	590	600
Contingent liability for Essentialis purchase price	6,066	5,649
Other long-term liabilities	38	—
Total liabilities	13,840	12,738
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at September 30, 2019 and December 31, 2018; zero shares issued and outstanding at September 30, 2019 and at December 31, 2018. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 31,793,292 and 31,755,169 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively.	32	32
Additional paid-in-capital	158,034	157,413
Accumulated deficit	(143,181)	(127,032)
Total stockholders' equity	14,885	30,413
Total liabilities and stockholders' equity	$ 28,725	$ 43,151

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 4,490	$ 2,092	$ 10,995	$ 4,986
General and administrative	1,615	1,558	5,322	5,191
Change in fair value of contingent consideration	28	228	417	589
Total operating expenses	6,133	3,878	16,734	10,766
Operating loss	(6,133)	(3,878)	(16,734)	(10,766)
Other income (expense)				
Cease-use income	—	—	—	6
Change in fair value of warrants liabilities	7,116	1,543	930	(1,549)
Loss from minority interest investment	(123)	—	(478)	—
Interest income, net	29	26	133	75
Total other income (expense)	7,022	1,569	585	(1,468)
Income (loss) from continuing operations	889	(2,309)	(16,149)	(12,234)
Loss from discontinued operations	—	(427)	—	(1,364)
Net income (loss)	$ 889	$ (2,736)	$ (16,149)	$ (13,598)
Income (loss) per common share from continuing operations:				
Basic	$ 0.03	$ (0.11)	$ (0.51)	$ (0.60)
Diluted	$ (0.19)	$ (0.11)	$ (0.53)	$ (0.60)
Loss per common share from discontinued operations:				
Basic	$ —	$ (0.02)	$ —	$ (0.07)
Diluted	$ —	$ (0.02)	$ —	$ (0.07)
Net income (loss) per common share:				
Basic	$ 0.03	$ (0.13)	$ (0.51)	$ (0.67)
Diluted	$ (0.19)	$ (0.13)	$ (0.53)	$ (0.67)
Weighted-average common shares outstanding used in per-share calculation:				
Basic	31,793,292	21,432,482	31,775,590	20,443,044
Diluted	32,443,647	21,432,482	32,235,528	20,443,044

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three and Nine Months Ended September 30, 2019 and 2018
(unaudited)
(In thousands except share data)

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2019	—	$ —	31,755,169	$ 32	$ 157,413	$ (127,032)	$ 30,413
Stock-based compensation					202		202
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			21,415	—	46		46
Net loss						(7,030)	(7,030)
Balances at March 31, 2019	—	—	31,776,584	32	157,661	(134,062)	23,631
Stock-based compensation					175		175
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			16,708	—	45		45
Net loss						(10,008)	(10,008)
Balances at June 30, 2019	—	—	31,793,292	32	157,881	(144,070)	13,843
Stock-based compensation					153		153
Net income						889	889
Balances at September 30, 2019	—	$ —	31,793,292	$ 32	158,034	$ (143,181)	$ 14,885

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2018	4,571	$ —	19,238,972	$ 19	$ 140,495	$ (113,697)	$ 26,817
Stock-based compensation					200		200
Issuance of common stock on conversion of series B convertible preferred shares	(1,000)	(—)	200,000	1	—		1
Issuance of restricted common stock for bonuses			99,217	—	159		159
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			49,519	—	82		82
Transaction costs for the 2017 PIPE common stock and warrant issuance.					(203)		(203)
Issuance of common stock held back on acquisition of Essentialis			180,667	—	—		—
Net loss						(3,804)	(3,804)
Balances at March 31, 2018	3,571	—	19,768,375	20	140,733	(117,501)	23,252
Stock-based compensation					199		199
Issuance of common stock on conversion of series B convertible preferred shares	(3,571)	(—)	714,200	—	(1)		(1)
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			27,925	—	54		54
Transaction costs for the 2017 PIPE common stock and warrant issuance.					203		203
Issuance of common stock held back on acquisition of Essentialis			903,367	1	(1)		—
Net loss						(7,058)	(7,058)
Balances at June 30, 2018	—	—	21,413,867	21	141,187	(124,559)	16,649
Stock-based compensation					231		231
Issuance of common stock to board members in lieu of cash payments for quarterly board fees			21,374	—	61		61
Net loss						-	-
Balances at September 30, 2018	—	$ —	21,435,241	$ 21	$ 141,479	$ (124,559)	$ 16,941

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (16,149)	$ (13,598)
Loss from discontinued operations	—	(1,364)
Loss from continuing operations	(16,149)	(12,234)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,468	1,473
Stock-based compensation expense	530	731
Board fees paid with common stock	91	197
Change in fair value of stock warrants	(930)	1,549
Change in fair value of contingent consideration	417	589
Operating loss on minority interest investment	478	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	154	142
Due from related party	55	—
Accounts payable	801	612
Accrued compensation and other liabilities	786	167
Net cash used in continuing operating activities	(12,299)	(6,774)
Net cash used in discontinued operating activities	—	(1,173)
Net cash used in operating activities	(12,299)	(7,947)
Cash flows from investing activities:		
Purchases of property and equipment	(16)	(6)
Security deposit on sublease	(59)	—
Proceeds from sale of minority interest investment in former subsidiary	500	—
Net cash provided by (used in) continuing investing activities	425	(6)
Net cash provided by (used in) investing activities	425	(6)
Cash flows from financing activities:		
Net cash provided by discontinued financing activities	—	1,525
Net cash provided by financing activities	—	1,525
Net decrease in cash, cash equivalents and restricted cash from continuing operations	(11,874)	(6,780)
Net increase in cash, cash equivalents and restricted cash from discontinued operations	—	352
Net decrease in cash, cash equivalents and restricted cash	(11,874)	(6,428)
Net increase in cash and cash equivalents included in current assets held for sale	—	(468)
Cash, cash equivalents and restricted cash, beginning of period	23,099	17,135
Cash, cash equivalents and restricted cash, end of period	$ 11,225	$ 10,239
Supplemental disclosure of non-cash investing and financing information		
Purchases of property and equipment with capital lease obligation	$ 28	$ -

See accompanying notes to condensed consolidated financial statements.

Note 1. Overview

Soleno Therapeutics, Inc. (the "Company" or "Soleno") was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. On May 8, 2017, Soleno received stockholder approval to amend its Amended and Restated Certificate of Incorporation to change its name from "Capnia, Inc." to "Soleno Therapeutics, Inc." The Company is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Its lead candidate, Diazoxide Choline Controlled Release tablets, or DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWS, is currently being evaluated in a Phase III clinical development program.

The Company initially established its operations as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz, and the CoSense® End-Tidal Carbon Monoxide Monitor, or CoSense, which measures End-Tidal Carbon Monoxide and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

On March 7, 2017, the Company completed its merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis, in accordance with the Merger Agreement by and between Soleno Therapeutics and Essentialis dated December 22, 2016, or the Merger Agreement. After the Merger, the Company's primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical-stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare diseases in which there is increased mortality and risk of cardiovascular and endocrine complications. Prior to the Merger, Essentialis's efforts were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically-regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and central nervous system diseases. Essentialis had tested DCCR as a treatment for PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Subsequent to the Merger with Essentialis described above, the Company determined to divest, sell or dispose of its business efforts focused on the development and commercialization of its Serenz and CoSense technologies. Accordingly, and pursuant to ASC 205-20-45-10, any assets and liabilities related to the discontinued activities of CoSense and Serenz were presented separately as held for sale items, and the related operations reported herein for the CoSense and Serenz activities are reported as discontinued operations in the statements of operations.

The Company's current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets, for the treatment of PWS, through late-stage clinical development.

Note 2. Going Concern and Management's Plans

The Company had a net loss of $16.1 million during the nine months ended September 30, 2019 and has an accumulated deficit of $143.2 million at September 30, 2019, resulting from having recurring losses since its inception. The Company had $8.2 million of working capital at September 30, 2019, and used $12.3 million of cash in its operating activities during the nine months ended September 30, 2019. The Company has financed its operations principally through issuances of equity securities.

On October 25, 2019, the Company sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million (see Note 12).

The accompanying condensed consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company expects to continue incurring losses for the foreseeable future and may be required to raise additional capital to complete its clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the Company's access to such capital resources is uncertain and is not assured. If the Company is unable to secure additional capital, it may be required to curtail its clinical trials and development of new products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and

meet its obligations. These measures could cause significant delays in the Company's efforts to complete its clinical trials and commercialize its products, which is critical to the realization of its business plan and the future operations of the Company. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should it be unable to continue as a going concern.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern within one year from the date of filing these financial statements.

The Company's current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

Note 3. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies during the nine months ended September 30, 2019 as compared to the significant accounting policies described in Note 3 of the "Notes to Consolidated Financial Statements" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. Below are those policies with current period updates.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the applicable rules and regulations of the SEC for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2018, has been derived from the audited consolidated financial statements at that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature that are necessary for a fair presentation of the results for the interim periods presented. The interim results are not necessarily indicative of the results for any future interim period or for the entire year.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K.

Recent Accounting Standards

Recently Adopted Accounting Standards

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*", to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Under the guidance, the measurement of equity-classified nonemployee awards is fixed at the grant date, which may lower the cost and reduce volatility in the income statement. This ASU was early adopted by the Company at the beginning of 2019. Its adoption did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, SEC adopted the final rule under SEC Release No. 33-10532, "*Disclosure Update and Simplification*", amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must now be provided in a note or separate statement. The Company has applied this new guidance to its condensed financial statements beginning in the first quarter of 2019.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02: "*Leases (Topic 842)*". ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. Upon adoption of ASU 2016-02, the Company may elect to apply the transition approach either as of the beginning of the earliest period presented in the financial statements – in which case it would restate its comparative periods, or as of the beginning of the period of adoption – in which case it would not restate its comparative periods. ASU 2016-02 requires the Company to capitalize most current operating lease obligations as right-of-use assets with a corresponding liability based on the present value of future operating lease obligations. Criteria for distinguishing leases between finance and operating are substantially similar to criteria for distinguishing between capital leases and operating leases in existing lease guidance. Lease agreements that are 12 months or less are permitted to be excluded from the balance sheet. Topic 842 includes a number of optional practical expedients that the Company may elect to apply. Expanded disclosures with additional qualitative and quantitative information will also be required. The adoption will include updates as provided under ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU 2018-10, Codification Improvements to Topic 842, Leases, ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors and ASU 2019-01, Leases (Topic 842): Codification Improvements. Topic 842 is effective for public entities with fiscal years beginning after December 15, 2018 and for all other entities for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company and elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act, Topic 842 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company will adopt the new lease standard effective beginning in the fiscal year beginning January 1, 2020 using a modified retrospective method and will not restate comparative periods. The Company currently believes that its operating lease commitments will be subject to the new standard and recognized as an operating lease liability and right-of-use asset upon the adoption of Topic 842, which will increase the Company's total assets and total liabilities in its condensed consolidated balance sheet.

In July 2017, the FASB issued ASU 2017-11, "*Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*", (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. The amendments in Part I of ASU 2017-11 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company and elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act, this ASU 2017-11 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*". The ASU modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. This ASU is effective for the Company beginning in 2020. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company has not yet evaluated the impact of adoption of this ASU on its condensed consolidated financial statements disclosures.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, restricted cash, cash equivalents and accounts payable, approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands).

	Fair Value Measurements at September 30, 2019			
	Total	Level 1	Level 2	Level 3
Liabilities				
Series A warrant liability	$ 25	$ 25	$ —	$ —
2017 PIPE warrant liability	3,667	—	—	3,667
2018 PIPE warrant liability	590	—	—	590
Essentialis purchase price contingency liability	6,066	—	—	6,066
Total common stock warrant and contingent consideration liability	$ 10,348	$ 25	$ —	$ 10,323

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
Liabilities				
Series A warrant liability	$ 49	$ 49	$ —	$ —
2017 PIPE warrant liability	4,563	—	—	4,563
2018 PIPE warrant liability	600	—	—	600
Essentialis purchase price contingency liability	5,649	—	—	5,649
Total common stock warrant and contingent consideration liability	$ 10,861	$ 49	$ —	$ 10,812

The Series A Warrant is a registered security that trades on the open market and the fair value of the Series A Warrant liability is based on the publicly quoted trading price of the warrants which is listed on and obtained from NASDAQ. Accordingly, the fair value of Series A Warrants is a Level 1 measurement. The fair value measurement of the Series C Warrants is based on significant inputs that are unobservable and thus represent Level 3 measurements. The Company's estimated fair value of the Series C Warrant liability is calculated using the Black-Scholes valuation model, which is equivalent to fair value computed using the Binomial Lattice Option Model. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates. The Company's estimated fair value of the 2017 PIPE Warrants and the 2018 PIPE Warrants was calculated using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility, the expected term, the expected dividend yield and the risk-free interest rate. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the Federal Drug Administration as well as reaching cumulative revenue milestones (see Note 10). The Level 3 estimates are based, in part, on subjective assumptions.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 1 and Level 3 warrants, which are treated as liabilities (dollars in thousands).

	Series A Warrant		Series C Warrant		2017 PIPE Warrants		2018 PIPE Warrants		Purchase Price
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Contingent Liability
Balance at December 31, 2018	485,121	$ 49	118,083	$ —	6,024,425	$ 4,563	513,617	$ 600	$ 5,649
Change in value of Series A Warrants	—	(24)	—	—	—	—	—	—	—
Change in value of 2017 PIPE Warrants	—	—	—	—	—	(896)	—	—	—
Change in value of 2018 PIPE Warrants	—	—	—	—	—	—	—	(10)	—
Change in value of contingent liability	—	—	—	—	—	—	—	—	417
Balance at September 30, 2019	485,121	$ 25	118,083	$ —	6,024,425	$ 3,667	513,617	$ 590	$ 6,066

Note 5. Warrant Liabilities

The Company has issued multiple warrant series, of which the Series A Warrants, Series C Warrants, the 2017 PIPE Warrants and the 2018 PIPE Warrants (the "Warrants") are considered liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging.*

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in *ASC 815*. As indicated below, the Company may be obligated to settle Warrants in cash in the case of a Fundamental Transaction (as defined in the Warrants).

The Company classified the Warrants, with a term greater than one year, as long-term liabilities at their fair value and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the Company's condensed consolidated statements of operations.

Series A Warrants

The Company has issued 489,921 Series A Warrants to purchase shares of its common stock at an exercise price of $32.50 per share in connection with the unit offering offered in the Company's initial public offering, or the IPO, in November 2014. The Series A Warrants are exercisable at any time prior to the expiration of the five-year term on November 12, 2019.

Upon the completion of the IPO, the Series A Warrants started trading on the NASDAQ under the symbol SLNOW. As the Series A Warrants are publicly traded, the Company uses the closing price on the measurement date to determine the fair value of the Series A Warrants. The Series A Warrants contract further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate volume weighted average price, or VWAP, of the shares into which each Warrant is convertible in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of these securities and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds related to the warrant financings to the registration payment arrangement. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

Since their issuance, a total of 4,800 Series A Warrants have been exercised. As of September 30, 2019, the fair value of the 485,121 outstanding Series A Warrants was approximately $25,000. The decrease of approximately $26,000 and $24,000 in fair value during the three and nine months ended September 30, 2019, respectively, was recorded as other income in the condensed consolidated statements of operations.

Series C Warrants

On March 5, 2015, the Company entered into separate agreements with certain Series B Warrant holders, who agreed to exercise their Series B Warrants to purchase an aggregate of 117,902 shares of the Company's common stock at an exercise price of $32.50 per share, resulting in the de-recognition of $6.7 million of the previously issued Series B Warrant liability and gross proceeds to the

Company of $3.8 million based on the exercise price of the Series B Warrants. In connection with this exercise of the Series B Warrants, the Company issued to each investor who exercised Series B Warrants, new Series C Warrants for the number of shares of the Company's common stock underlying the Series B Warrants that were exercised. Each Series C Warrant is exercisable at $31.25 per share and will expire on March 5, 2020. The Series C Warrants contract further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate volume weighted average price, or VWAP, of the shares into which each Warrant is convertible in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of these securities and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds related to the warrant financings to the registration payment arrangement. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

In April 2015, the Company issued a tender offer to the remaining holders of Series B Warrants to induce the holders to cash exercise the outstanding Series B Warrants in exchange for new Series C Warrants with an exercise price of $31.25 per share that expire on March 5, 2020. The tender offer was extended to Series B Warrant holders under a registration statement filed with the SEC on Form S-4, which was declared effective on June 25, 2015 and expired on July 24, 2015. During July 2015, certain Series B Warrant holders tendered their Series B Warrants under the tender offer, which resulted in the issuance of 181 shares of the Company's common stock, the issuance of 181 Series C Warrants and proceeds to the Company of approximately $6,000.

The Series C Warrants are exercisable into 118,083 shares of the Company's common stock. As of September 30, 2019, the fair value of the Series C Warrants was determined to be zero, consistent with the balance as of December 31, 2018 and June 30, 2019.

The Company has calculated the fair value of the Series C Warrants using a Black-Scholes pricing model. The Black-Scholes pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The Company used the following inputs.

	September 30, 2019	December 31, 2018
Volatility	90%	90%
Contractual term (years)	0.42	1.17
Expected dividend yield	—%	—%
Risk-free rate	1.85%	2.60%

Warrants Issued as Part of the Units in the 2017 PIPE Offering

The 2017 PIPE Warrants were issued on December 15, 2017 in the 2017 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2017 PIPE Offering, and entitle the holder to purchase one share of the Company's common stock at an exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2017 PIPE Warrants and terminating at the earlier of December 15, 2020 or 30 days following positive Phase III results for the DCCR tablet in PWS.

The exercise price and number of shares of common stock issuable upon exercise of the 2017 PIPE Warrants may be adjusted in certain circumstances, including the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2017 PIPE Warrants will not be reduced below $1.72.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of September 30, 2019, the fair value of the 2017 PIPE Warrants was estimated at $3.7 million. The decrease in the fair value of the liability for the 2017 PIPE Warrants of $6.5 million and approximately $896,000 during the three and nine months ended September 30, 2019, respectively, was recorded as other income in the condensed consolidated statements of operations. The decrease in the fair value of the liability for the 2017 PIPE Warrants of approximately $1.4 million during the three months ended September 30, 2018 and the increase in the fair value of $1.6 million during the nine months ended September 30, 2018, were recorded as other income and expense in the condensed consolidated statements of operations.

The Company has calculated the fair value of the 2017 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

	September 30, 2019	December 31, 2018
Volatility	85%	75%
Contractual term (years)	1.2	2.0
Expected dividend yield	—%	—%
Risk-free rate	1.80%	2.51%

Warrants Issued as Part of the Units in the 2018 PIPE Offering

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and entitle the holders of each of the 10,272,375 units to purchase 0.05 shares of the Company's common stock at an exercise price equal to $2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2018 PIPE Warrants and terminating on December 21, 2023.

The exercise price and number of shares of common stock issuable upon exercise of the 2018 PIPE Warrants may be adjusted in certain circumstances, including the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2018 PIPE Warrants will not be reduced below $2.00.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of September 30, 2019, the fair value of the 2018 PIPE Warrants was estimated at approximately $590,000. The approximate $555,000 and $10,000 decrease in the fair value of the liability for the 2018 PIPE Warrants during the three and nine months ended September 30, 2019, respectively, was recorded as other income in the condensed consolidated statements of operations.

The Company has calculated the fair value of the 2018 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

	September 30, 2019	December 31, 2018
Volatility	85%	75%
Contractual term (years)	4.2	5.0
Expected dividend yield	—%	—%
Risk-free rate	1.56%	2.51%

The Monte Carlo simulation of a geometric Brownian motion model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates.

- *Volatility:* The Company calculates the estimated volatility rate based on the volatilities of common stock of comparable companies in its industry.
- *Contractual term:* The expected life of the warrants, which is based on the contractual term of the warrants.
- *Expected dividend yield:* The Company has never declared or paid any cash dividends and does not currently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.
- *Risk-free rate:* The risk-free interest rate is based on the U.S. Treasury rate for similar periods as those of expected volatility.

Note 6. Commitments and Contingencies

Facility Leases

The Company's previous operating lease for its headquarters facility office space in Redwood City, California, terminated in August 2019. In July 2019, the Company executed a non-cancellable lease agreement for 6,368 square feet of new space in Redwood City, California, which began in September 2019 and expires in May 2021. The lease also provides the Company with the right to use office furniture in the space and allows the purchase of this furniture at the end of the lease term for $1. The lease agreement requires monthly lease payments of approximately $29,000 beginning in November of 2019, with an increase to approximately $30,000 per month in September of 2020. The Company has accounted for the new lease as an operating lease for the office space and a capital lease for the office furniture, based on their relative fair values. The gross value of office furniture under this capital lease was approximately $27,000.

Rent expense was approximately $65,000 and $78,000 during the three months ended September 30, 2019 and 2018, respectively, net of sublease income of approximately $43,000 and $39,000, respectively. Rent expense was approximately $167,000 and $246,000 during the nine months ended September 30, 2019 and 2018, respectively, net of sublease income of approximately $173,000 and $237,000, respectively.

The following is a schedule by year of future minimum lease payments under the Company's lease agreement as of September 30, 2019 (in thousands):

	Capital Lease	Operating Lease	Total
Remaining of 2019	$ 3	$ 56	$ 59
2020	19	336	355
2021	8	143	151
Total	30	$ 535	$ 565
Less: Amount representing interest	(2)		
Present value of minimum lease payments	$ 28		

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 7. CoSense Joint Venture Agreement and Discontinued Operations

In December 2017, the Company entered into a joint venture with OptAsia Healthcare Limited, or OAHL, with respect to its CoSense product by agreeing to sell shares of Capnia, its then wholly-owned subsidiary, to OAHL. CoSense was Soleno's first Sensalyze Technology Platform product to receive 510(k) clearances from the FDA and CE Mark certification. CoSense measures CO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. The Company's entry into the joint venture resulted from a comprehensive review of strategic alternatives for its legacy products and product candidates following its transition to a primarily therapeutic drug product company. The terms of the Joint Venture Agreement provide that OAHL would invest up to a total of $2.2 million in Capnia's common shares on an incremental quarterly basis commencing in December 2017. OAHL was also responsible for funding a portion of the Capnia operations. The Joint Venture Agreement provided that Capnia would issue shares of common stock to OAHL based on a negotiated price of $1.00 per share when the cumulative investment made by OAHL equaled or exceeded $1.2 million. For financial reporting purposes, Capnia's assets, liabilities and results of operations had historically been consolidated with those of the Company.

During October 2018, the Company and OAHL determined and agreed that the cumulative investment made by OAHL exceeded $1.2 million during the quarter ended September 30, 2018. Accordingly, on October 16, 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares. After the share issuance the Company no longer held a controlling interest in Capnia and resulted in the deconsolidation of Capnia's financial statements from those of the Company and a $2.0 million gain was recognized in the fourth quarter of 2018 as a result of the deconsolidation. Of this amount, $1.2 million

related to the remeasurement of the Company's retained interest in the joint venture to fair value which was measured based on the negotiated price of $1.00 per share for Soleno's remaining ownership of 1,480,000 shares less a 23% discount for lack of control over Capnia. The total gain was included in other income from continuing operations on the Company's consolidated statements of operations. The remaining 47% investment in Capnia was classified as an equity method investment and presented as a Minority interest investment in former subsidiary in the condensed consolidated balance sheet. The balance of Minority interest investment in former subsidiary decreased by approximately $156,000 and $511,000 during the three and nine months ended September 30, 2019, respectively, as a result of the Company recording its share of Capnia's net losses during the period, which is included in the line titled "Loss from minority interest investment" in the Company's condensed consolidated statements of operations. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon Investments LLC ("Sinon") for a total purchase price of $500,000. As of the sale date, the Company had a minority interest investment in former subsidiary balance of approximately $467,000, after recording approximately $511,000 for its share of Capnia's losses during 2019 up until the date of sale. A gain of approximately $33,000 was recognized upon the sale and is presented, together with the Company's share of Capnia's net losses during the period, in the condensed consolidated statements of operations in the line titled "Loss from minority interest investment". Following the transaction, the Company has no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

There were no assets or liabilities held for sale as of September 30, 2019, or December 31, 2018, after the deconsolidation of Capnia in October 2018, and no discontinued operations during the three and nine months ended September 30, 2019. The components of the Statements of Operations presented as Discontinued Operations during the three and nine months ended September 30, 2018 follow (in thousands).

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Product revenue	$ 6	$ 60
Cost of product revenue	2	30
Gross profit (loss)	4	30
Expenses		
Research and development	306	1,009
Sales and marketing	1	25
General and administrative	124	360
Total expenses	431	1,394
Net loss from discontinued operations	$ (427)	$ (1,364)

Stock-based compensation expense of approximately $20,000 and $58,000 was classified in discontinued operations for the three and nine months ended September 30, 2018, respectively. There were no discontinued operations during the three and nine months ended September 30, 2019.

Note 8. Stockholders' Equity

Equity Incentive Plans

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan, or the 2014 Plan, and together, the Plans. The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity Incentive Plan has been closed to new issuances. Under the 2014 Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance units or performance shares to employees, directors, advisors, and consultants. Options granted under the 2014 Plan may be incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees, including officers and directors.

The Board of Directors has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. The vesting period is normally monthly over a period of 4 years from the vesting date. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The terms and conditions governing restricted stock units is at the sole discretion of the Board. As of September 30, 2019, a total of 905,532 shares are available for future grant under the 2014 Plan.

The Company recognized stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants for the three and nine months ended September 30, 2019 of approximately $153,000 and $530,000, respectively. Stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants during the three and nine months ended September 30, 2018 was approximately $231,000 and $789,000, respectively, of which approximately $20,000 and $58,000, was recorded in discontinued operations in the three and nine months ended September 30, 2018, respectively. There were no discontinued operations during the nine months ended September 30, 2019. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements during any of the periods presented.

Stock compensation expense was allocated between departments in continuing operations as follows (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 42	$ 34	$ 124	$ 174
General and administrative	111	177	406	557
Total	$ 153	$ 211	$ 530	$ 731

Stock Options

The Company granted options to purchase 565,785 and 736,086 of the Company's common stock during the nine months ended September 30, 2019 and 2018, respectively. There were no options granted during the three months ended September 30, 2019 or 2018. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	Nine Months Ended September 30,	
	2019	2018
Expected life (years)	5.5-6.1	5.5-6.02
Risk-free interest rate	1.9%-2.6%	2.7%-2.8%
Volatility	70%-71%	70%
Dividend rate	— %	— %

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates:

- *Expected life:* The expected life of stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company does not believe it is able to rely on historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of stock options. Therefore, it has opted to use the "simplified method" for estimating the expected term of options.
- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Volatility:* The estimated volatility rate based on the volatilities of common stock of comparable companies in the Company's industry.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option transactions for the nine months ended September 30, 2019 as issued under the Plans:

	Shares Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)
Balance at December 31, 2018	1,150,961	1,667,153	$ 6.03	8.27
Additional shares authorized	223,742			
Options granted	(565,785)	565,785	$ 1.82	
Options exercised	—	—	—	
Options canceled/forfeited	96,614	(96,614)	$ 4.75	
Balance at September 30, 2019	905,532	2,136,324	$ 4.97	8.02
Options vested at September 30, 2019		1,104,712	$ 7.79	7.34
Options vested and expected to vest at September 30, 2019		2,136,324	$ 4.97	8.02

The weighted-average grant date fair value of options granted was $1.17 and $1.09 per share for the nine months ended September 30, 2019 and 2018, respectively. At September 30, 2019 total unrecognized employee stock-based compensation was $1.2 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.5 years. As of September 30, 2019, the outstanding stock options had an intrinsic value of zero.

Restricted Stock Units

There were 99,217 restricted stock units granted by the Company during the nine months ended September 30, 2018 to employees and nonemployees. The shares were 100% vested on the grant date and were valued based on the Company's common stock price on the grant date, with approximately $159,000 of the related stock-based compensation expense recognized at that time. There were no restricted stock units granted by the Company during the nine months ended September 30, 2019.

2014 Employee Stock Purchase Plan

The Company's board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan, or the ESPP. The ESPP has become effective, and the board of directors will implement commencement of offers thereunder in its discretion. A total of 27,967 shares of the Company's common stock has been made available for sale under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that the board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of the Company's common stock on the first day of such year;
- 55,936 shares; or
- such amount as determined by the board of directors.

As of September 30, 2019, there were no purchases by employees under this plan.

Series D Warrants

The Company issued 256,064 Series D Warrants in October 2015, which are exercisable into 586,182 shares of the Company's common stock, with an exercise price of $12.30 and a term of five years expiring on October 15, 2020. The Company's Series D Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the warrants and underlying shares. The Company is required to comply with certain requirements to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. The Series D Warrant agreement further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate VWAP of the shares into which each Series D Warrant is convertible in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of this securities agreement and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds

to the registration payment arrangement. The Series D Warrant agreement specifically provides that under no circumstances will the Company be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise.

Accounting Treatment

The Company accounts for the Series D Warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging.* As indicated above, the Company is not required under any circumstance to settle any Series D Warrant exercise for cash. The Company has therefore classified the value of the Series D Warrants as permanent equity.

Other Common Stock Warrants

As of September 30, 2019, the Company had 102,070 common stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of $24.35 and a term of 10 years expiring in November 2024. The Company also had 16,500 common stock warrants issued to the underwriter in the Company's IPO, with an exercise price of $35.70 and a term of 10 years, expiring in November 2024.

Note 9. Net income (loss) per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock actually outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding and dilutive potential common stock that would be issued upon the exercise of common stock options and warrants.

The following table presents the calculation of basic and diluted earnings per share (in thousands, except per-share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Income (loss) from continuing operations	$ 889	$ (2,309)	$ (16,149)	$ (12,234)
Loss from discontinued operations	—	(427)	—	(1,364)
Net income (loss) - basic	889	(2,736)	(16,149)	(13,598)
Less: noncash income from change in fair value of warrants	7,090	—	906	—
Net loss - diluted	$ (6,201)	$ (2,736)	$ (17,055)	$ (13,598)
Denominator:				
Basic weighted-average common shares outstanding	31,793,292	21,432,482	31,775,590	20,443,044
Effect of dilutive securities:				
Options to purchase common stock	260,882	—	236,395	—
Warrants	389,473	—	223,543	—
Diluted weighted-average common shares outstanding	32,443,647	21,432,482	32,235,528	20,443,044
Income (loss) per common share from continuing operations:				
Basic	$ 0.03	$ (0.11)	$ (0.51)	$ (0.60)
Diluted	$ (0.19)	$ (0.11)	$ (0.53)	$ (0.60)
Loss per common share from discontinued operations:				
Basic	$ -	$ (0.02)	$ -	$ (0.07)
Diluted	$ -	$ (0.02)	$ -	$ (0.07)
Net income (loss) per common share:				
Basic	$ 0.03	$ (0.13)	$ (0.51)	$ (0.67)
Diluted	$ (0.19)	$ (0.13)	$ (0.53)	$ (0.67)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented because such securities have an antidilutive impact, either due to the losses reported or because the exercise price was greater than the average market price of the common shares during the period.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070	102,070	102,070
Options to purchase common stock	1,875,442	1,667,896	1,899,930	1,667,896
Warrants issued in 2009 to purchase common stock	—	1,851	—	1,851
Warrants issued to underwriter to purchase common stock	16,500	16,500	16,500	16,500
Series A warrants to purchase common stock	485,121	485,121	485,121	485,121
Series C warrants to purchase common stock	118,083	118,083	118,083	118,083
Series D warrants to purchase common stock	586,162	586,182	586,162	586,182
2017 PIPE warrants	5,665,548	6,024,425	5,818,443	6,024,425
2018 PIPE warrants	483,021	—	496,056	—
Total	9,331,947	9,002,128	9,522,365	9,002,128

Note 10. Fair Value of Contingent Consideration

On March 7, 2017, the Company acquired Essentialis through the Merger of the Company's wholly-owned subsidiary, Company E Merger Sub, Inc., a Delaware corporation, or the Merger Sub, whereby Merger Sub merged into Essentialis, with Essentialis surviving the Merger as a wholly owned subsidiary of the Company.

The transaction has been accounted for as an asset acquisition under the acquisition method of accounting. The amendments in ASU 2017-01 provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets and activities is not a business.

Upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, the Company is obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders. The agreement to pay cash upon the achievement of the commercial milestones results in the recognition of a contingent consideration. The fair value of the contingent cash consideration is based on the Company's analysis of the likelihood of the drug indication moving from phase II through approval in the Federal Drug Administration approval process and then reaching the cumulative revenue milestones.

Management engaged independent professional assistance and advice in order to assess the fair value of the contingent stock and cash consideration as of March 7, 2017 and December 31, 2017. During the process of determining the fair value of the contingent consideration at December 31, 2017, the Company became aware that certain of the subjective assumptions made at the time of the initial valuation should be modified based upon management's increased understanding of the commercial capabilities of the DCCR drug. Accordingly, the Company determined that it was appropriate to adjust the provisional valuation amounts recorded for the contingent stock and cash consideration made at the inception in March 2017. As a result, the value of the contingent cash consideration to be paid upon completing successive sales milestones increased and the value of the contingent stock consideration payable upon timing milestones was reduced; the resulting combined change to the total contingent consideration was not material. The initial valuation of the contingent consideration determined the fair value of the contingent stock consideration to be $4.2 million and the fair value of the contingent cash consideration to be $1.1 million, for the combined value of $5.3 million. The revision of the initial valuation of the contingent consideration, made within the measurement period, determined the fair value of the contingent stock consideration to be $2.7 million and the fair value of the contingent cash consideration to be $2.6 million, for the combined value of $5.3 million.

Also subsequent to March 7, 2017 and prior to December 31, 2017, the Company completed its assessment of the tax effect on the net assets acquired by obtaining the independent study and report regarding the change in control in the previously outstanding stock of Essentialis. As a result of completing the study, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's federal and state operating loss carryforwards were limited, which required the Company to record a net deferred tax liability in the amount of $1.7 million, deferred to future periods, as an element of the assets

acquired. As a consequence of recording the net deferred tax liability, the Company's valuation allowance was reduced by $1.7 million, which resulted in the provision for income tax benefit and an increase in the value of the intangible asset acquired.

The probability weighted milestone payments were discounted to determine the present value of future cash payments. The analysis utilized the weighted average cost of capital, or WACC, discount rate which was estimated to be 20%.

The fair value of the liability for the contingent consideration payable by the Company achieving the commercial sales milestones of $100 million and $200 million was initially established as $2.6 million at the time of the merger and $6.0 million at September 30, 2019, based on the Company's assessment that it could reach the commercial sales milestones in 2024 and 2026, respectively.

Note 11. Compensation Plan for Board Members

In 2017, the Compensation Committee of the Board of Directors recommended, and the Board approved a revised compensation plan pursuant to which each board member may choose to receive payment of all annual board fees in common stock of the Company. Net payment to the Board of Directors in shares of the Company's common stock is made after the close of the quarter in which the compensation is earned, with the appropriate federal and state taxes thereon paid in cash directly to the taxing authority. Generally, directors who are citizens and residents of the United States receive their annual board fees in the form of stock, and directors who are not citizens and residents of the United States receive payment of their annual board fees in cash. During the three months ended September 30, 2019 and 2018, the Company issued zero and 21,374 shares, respectively, of common stock to its Board members for fees earned. During the nine months ended September 30, 2019 and 2018, the Company issued 38,123 and 98,818 shares, respectively, of common stock to its Board members for fees earned. The appropriate federal and state taxes thereon was paid in cash directly to the taxing authority.

Note 12. Subsequent Events

The Company has evaluated its subsequent events from September 30, 2019 through the date these condensed consolidated financial statements were issued and has determined that there are no subsequent events requiring disclosure in these condensed consolidated financial statements other than the item noted below.

Public Offering

On October 25, 2019, the Company sold 12,841,667 shares of its common stock, including 1,675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares, at a public offering price of $1.20 per share. The net proceeds of the offering were $14.5 million, after deducting the underwriting discount and other offering expenses.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation

The interim consolidated financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2018, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Form 10-K for the year ended December 31, 2018. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate, Diazoxide Choline Controlled Release tablets, or DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWS, is currently being evaluated in a Phase III clinical development program.

We initially established our operations as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz, and the CoSense® End-Tidal Carbon Monoxide Monitor, or CoSense, which measures End-Tidal Carbon Monoxide and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

On December 22, 2016, we entered into the Merger Agreement with Essentialis. Essentialis's efforts prior to the Merger were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and central nervous system diseases. Essentialis had tested DCCR as a treatment for PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the U.S. as well as in the E.U. Consummation of the Merger was subject to various closing conditions, including our consummation of a financing of at least $8.0 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of our stockholders, which was held on March 6, 2017.

Subsequent to the Merger with Essentialis described above, we determined to divest, sell or dispose of our business efforts focused on the development and commercialization of our Serenz and CoSense technologies. As a result, we now primarily focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development. Accordingly, and pursuant to ASC 205-20-45-10, any assets and liabilities related to the discontinued activities of CoSense and Serenz were presented separately as held for sale items, and the related operations reported herein for the CoSense and Serenz activities are reported as discontinued operations in the statements of operations.

On December 4, 2017, we and our then wholly-owned subsidiary Capnia, entered into a joint venture with OptAsia Healthcare Limited, or OAHL, with the purpose of developing and commercializing CoSense with the intent to transfer ownership of Capnia to OAHL. During October 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares, after which we no longer held a controlling interest in Capnia. Accordingly, we deconsolidated Capnia's financial statements from ours and our remaining minority interest in Capnia was reported as a Minority interest investment in our consolidated balance sheet. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon Investments LLC ("Sinon"). Following the transaction, the Company has no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

On July 30, 2018, the FDA has granted Fast Track designation to DCCR for the treatment of PWS. We are currently conducting a Phase III clinical trial of DCCR for the treatment of PWS.

As of September 30, 2019, we had an accumulated deficit of $143.2 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of our neonatology products, therapeutic products, other diagnostic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated approximately $2,000 of revenue from the 2013 license agreement pertaining to Serenz, approximately $2.7 million in revenue from our neonatology products and approximately $0.2 million in government grants; these activities are reported as discontinued operations in our accompanying consolidated financial statements. We may never be successful in commercializing our novel therapeutic and in divesting, selling or otherwise disposing of our existing neonatology products or related therapeutic products. Accordingly, we expect to incur significant

losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 3 of our most recent Form 10-K.

Results of Continuing Operations

Comparison of the three months ended September 30, 2019 and 2018, from continuing operations

	Three Months Ended September 30,		Increase (decrease)	
	2019	2018	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 4,490	$ 2,092	$ 2,398	115%
General and administrative	1,615	1,558	57	4%
Change in fair value of contingent consideration	28	228	(200)	88%
Total operating expenses	6,133	3,878	2,255	58%
Operating loss	(6,133)	(3,878)	(2,255)	58%
Other income (expense)				
Cease-use income	—	—	—	n/a
Change in fair value of warrants liabilities	7,116	1,543	5,573	361%
Loss from minority interest investment	(123)	—	(123)	n/a
Interest income, net	29	26	3	12%
Total other income	7,022	1,569	5,453	348%
Income (loss) from continuing operations	889	(2,309)	3,198	139%
Loss from discontinued operations	—	(427)	427	100%
Net income (loss)	$ 889	$ (2,736)	$ 3,625	132%

Revenue

We have yet not commenced commercialization of DCCR, our current sole product, and accordingly, through September 30, 2019, have generated no revenue from continuing operations.

Research and development expense

Research and development expense of $4.5 million for the three months ended September 30, 2019, increased by $2.4 million over the three months ended September 30, 2018, resulting primarily from the initiation of the Phase III clinical trial in May 2018. As of September 30, 2019, we have 26 clinical trial sites initiated compared to 10 as of September 30, 2018. As a result, we have incurred increased clinical site costs, consulting costs, lab costs, and manufacturing costs for DCCR production.

General and administrative expense

General and administrative expense of $1.6 million for the three months ended September 30, 2019, was generally consistent with the expense during the three months ended September 30, 2018.

Change in fair value of contingent consideration

The approximate $28,000 for the three months ended September 30, 2019, represents the increase in the fair value of the additional consideration that we expect to pay Essentialis stockholders based on our assessment of the expected likelihood of achieving commercial sales milestones of $100 million and $200 million in future years.

Other income (expense)

Other income of $7.0 million in the three months ended September 30, 2019, increased by $5.5 million from the three months ended September 30, 2018. This increase was primarily due to a $5.6 million larger decrease in the fair value of our outstanding warrants during the three months ended September 30, 2019 compared to the three months ended September 30, 2018. This change in valuation was primarily a result of the fluctuations of our common stock price. This increase was partially offset by an approximate $123,000 loss recorded on our minority interest investment in Capnia, our former subsidiary, during the three months ended September 30, 2019, which includes approximately $156,000 for our share of Capnia's net losses during the period, partially offset by a gain of approximately $33,000 recognized upon the sale of the investment.

Comparison of the nine months ended September 30, 2019 and 2018, from continuing operations

	Nine Months Ended September 30,		Increase (decrease)	
	2019	2018	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 10,995	$ 4,986	$ 6,009	121%
General and administrative	5,322	5,191	131	3%
Change in fair value of contingent consideration	417	589	(172)	29%
Total operating expenses	16,734	10,766	5,968	55%
Operating loss	(16,734)	(10,766)	(5,968)	55%
Other income (expense)				
Cease-use income	—	6	(6)	100%
Change in fair value of warrants liabilities	930	(1,549)	2,479	160%
Loss from minority interest investment	(478)	-	(478)	n/a
Interest income, net	133	75	58	77%
Total other income (expense)	585	(1,468)	2,053	140%
Loss from continuing operations	(16,149)	(12,234)	(3,915)	32%
Loss from discontinued operations	-	(1,364)	1,364	100%
Net loss	$ (16,149)	$ (13,598)	$ (2,551)	19%

Revenue

We have yet not commenced commercialization of DCCR, our current sole product, and accordingly, through September 30, 2019, have generated no revenue from continuing operations.

Research and development expense

Research and development expense of $11.0 million for the nine months ended September 30, 2019, increased by $6.0 million over the nine months ended September 30, 2018, resulting primarily from the initiation of the Phase III clinical trial in May 2018. As of September 30, 2019, we have 26 clinical trial sites initiated and, as a result, have incurred increased clinical site costs, consulting costs, lab costs, and manufacturing costs for DCCR production. Our efforts until May 2018 were focused on preparation of the trials.

General and administrative expense

General and administrative expense of $5.3 million for the nine months ended September 30, 2019 was generally consistent with the expense during the nine months ended September 30, 2018.

Change in fair value of contingent consideration

The approximate $417,000 for the nine months ended September 30, 2019, represents the increase in the fair value of the additional consideration that we expect to pay Essentialis stockholders based on our assessment of the expected likelihood of achieving commercial sales milestones of $100 million and $200 million in future years.

Other income (expense)

Other income of approximately $585,000 in the nine months ended September 30, 2019, increased by $2.1 million from other expense during the nine months ended September 30, 2018. This increase was primarily due to a $2.5 million larger decrease in the fair value of our outstanding warrants during the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018. This change in valuation was primarily a result of the fluctuations of our common stock price. During the nine months ended September 30, 2019, the Company also had $58,000 more of net interest income as compared to the nine months ended September 30, 2018. These increases were partially offset by an approximate $478,000 loss recorded on our minority interest investment in Capnia, our former subsidiary, during the nine months ended September 30, 2019, which includes approximately $511,000 for our share of Capnia's net losses during the period, partially offset by a gain of approximately $33,000 recognized upon the sale of the investment.

Results of Discontinued Operations

Discontinued operations during 2018 consist of our activities previously dedicated to the development and commercialization of innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz; CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly; and, products that included temperature probes, scales, surgical tables and patient surfaces. In March 2017 we determined to divest, sell or otherwise dispose of the CoSense, Neo Force, Inc., and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. The discontinued operations for the development and commercialization of innovative diagnostic devices and therapeutics are summarized below.

Comparison of the three and nine months ended September 30, 2019 and 2018, from discontinued operations

	Three Months Ended September 30,		Increase (decrease)	
	2019	2018	Amount	Percentage
	(in thousands)			
Product revenue	$ —	$ 6	$ (6)	100%
Cost of product revenue	—	2	(2)	100%
Gross profit (loss)	—	4	(4)	100%
Expenses:				
Research and development	—	306	(306)	100%
Sales and marketing	—	1	(1)	100%
General and administrative	—	124	(124)	100%
Total expenses	—	431	(431)	100%
Net loss from discontinued operations	$ —	$ (427)	$ 427	100%

	Nine Months Ended September 30,		Increase (decrease)	
	2019	2018	Amount	Percentage
	(in thousands)			
Product revenue	$ —	$ 60	$ (60)	100%
Cost of product revenue	—	30	(30)	100%
Gross profit (loss)	—	30	(30)	100%
Expenses:				
Research and development	—	1,009	(1,009)	100%
Sales and marketing	—	25	(25)	100%
General and administrative	—	360	(360)	100%
Total expenses	—	1,394	(1,394)	100%
Net loss from discontinued operations	$ —	$ (1,364)	$ 1,364	100%

All discontinued operations activity during the three and nine months ended September 30, 2018 related to Capnia and its CoSense products. During October 2018, Capnia issued 53% of its outstanding shares of common stock to OAHL, leaving us with a noncontrolling interest. Accordingly, we deconsolidated Capnia's financial statements from ours and our remaining minority interest in Capnia was reported as a minority interest investment in our condensed consolidated balance sheet. During September 2019, the Company sold its remaining 47% investment in Capnia to Sinon Investments LLC ("Sinon"). As Capnia is no longer a consolidated entity of ours, there is no corresponding discontinued operations activity for the three or nine months ended September 30, 2019.

Liquidity and Capital Resources

We had a net loss of $16.1 million during the nine months ended September 30, 2019, and an accumulated deficit of $143.2 million at September 30, 2019, from having incurred losses since our inception. We had $8.2 million of working capital at September 30, 2019, and used $12.3 million of cash in operating activities during the nine months ended September 30, 2019. We have financed our operations principally through issuances of equity securities. On October 25, 2019, the Company sold 12,841,667 shares of common stock in an underwritten public offering at a price of $1.20 per share for net proceeds of $14.5 million.

We have continued to focus on expense control, including reducing legal fees and implementing a plan to allow Board members to receive common stock, in lieu of cash payments.

We expect to continue incurring losses for the foreseeable future and may be required to raise additional capital to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the access to such capital resources is uncertain and is not assured. If we are unable to secure additional capital, we may be required to curtail our clinical trials and development of new products and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to complete clinical trials and commercialize our products, which is critical to the realization of our business plan and our future operations. These matters raise substantial doubt about our ability to continue as a going concern within one year from the date of filing this quarterly report.

The accompanying condensed consolidated financial statements have been prepared under the assumption we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in continuing operating activities	$ (12,299)	$ (6,774)
Net cash used in discontinued operating activities	-	(1,173)
Net cash used in operating activities	(12,299)	(7,947)
Net cash provided by (used in) continuing investing activities	425	(6)
Net cash provided by (used in) investing activities	425	(6)
Net cash provided by discontinued financing activities	—	1,525
Net cash provided by financing activities	—	1,525
Net increase (decrease) in cash, cash equivalents and restricted cash		
Continuing operations	(11,874)	(6,780)
Discontinued operations	—	352
Net decrease in cash, cash equivalents and restricted cash	$ (11,874)	$ (6,428)

Continuing Operations

Cash used in operating activities

During the nine months ended September 30, 2019, operating activities used net cash of $12.3 million, which was primarily due to the loss from continuing operations of $16.1 million and approximately $513,000 for the change in fair value of stock warrants and contingent consideration. These uses are adjusted for non-cash expenses of approximately $1.5 million for depreciation and amortization, approximately $621,000 of expenses paid with common stock or equity awards, and an approximate $478,000 operating loss on minority interest investment. Additionally, the usage of cash during the nine months ended September 30, 2019, was reduced by $1.8 million due to decreases in prepaid expenses and other current assets and amounts due from related parties, and increases in accounts payable, and accrued compensation and other liabilities.

During the nine months ended September 30, 2018, operating activities used net cash of $6.8 million, which was primarily due to the loss from continuing operations of $12.2 million, adjusted for non-cash expenses of $1.5 million for depreciation and amortization, approximately $928,000 of expenses paid with common stock or equity awards, and $2.1 million for the change in fair value of stock warrants and contingent consideration. Additionally, the usage of cash during the nine months ended September 30, 2018 was reduced by approximately $921,000 from an increase in accounts payable, accrued compensation and other current liabilities and a decrease in prepaid expenses.

Cash used in investing activities

During the nine months ended September 30, 2019, investing activities related to continuing operations provided cash of approximately $425,000. This was primarily a result of the $500,000 that we received for the sale of our 47% investment in Capnia to Sinon in September 2019. This was partially offset by cash that was used for a deposit of approximately $59,000 related to the new lease that we entered into in July 2019 for 6,368 square feet of new space in Redwood City, California. There was minimal cash used in the nine months ended September 30, 2019 and September 30, 2018 for the costs of acquiring property and equipment.

Cash provided by financing activities

There were no financing activities related to continued operations during the nine months ended September 30, 2019 and September 30, 2018.

As of September 30, 2019, we had cash and cash equivalents of $11.2 million.

We believe that we do not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. We expect to continue incurring losses for the foreseeable future and may be required to raise additional capital to pursue our therapeutic product development initiatives. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of this report.

Discontinued Operations

Cash used in operating activities

There were no discontinued operations during the nine months ended September 30, 2019, after the deconsolidation of Capnia in October 2018. During the nine months ended September 30, 2018, we used net cash of $1.2 million for discontinued operating activities, resulting primarily from the loss from discontinued operations of $1.4 million partially offset by approximately $71,000 of non-cash expenses associated with stock compensation and depreciation and amortization. Changes in the discontinued operations working capital accounts also offset the cash used by approximately $120,000, primarily from the decrease in various asset balances.

Cash provided by investing activities

There were no investing activities related to discontinued operations during the nine months ended September 30, 2019 or September 30, 2018.

Cash provided by financing activities

There were no financing activities related to discontinued operations during the nine months ended September 30, 2019. Net cash provided by financing activities related to discontinued operations was $1.5 million during the nine months ended September 30, 2018, representing the cash received during the period from our joint venture partner to fund the operations of Capnia. Capnia was deconsolidated in October 2018 upon a transfer of a controlling interest in the entity to our joint venture partner, OAHL.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have not been any material changes to our exposure to market risk during the nine months ended September 30, 2019. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Form 10-K.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the third fiscal quarter ended September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, even if determined effective and no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives to prevent or detect misstatements. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties. A description of factors that could materially affect our business, financial condition, or operating results is included under "Risk Factors" in Item 1A of Part I of our 2018 Annual Report on Form 10-K and is incorporated herein by reference. There have been no material changes to the risk factor disclosure since our 2018 Annual Report on Form 10-K. The risk factors described in our Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial conditions and/or operating results. If any of these risks actually occur, our business, operating results and financial condition could be harmed, and the value of our stock could go down. This means you could lose all or a part of your investment.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

The Company's current focus is on the development of Diazoxide Choline Controlled-Release, or DCCR, for patients with Prader-Willi Syndrome, or PWS. On July 30, 2018, the DCCR development program for PWS was granted Fast Track designation by the FDA.

DCCR is a once-a-day tablet formulation, which is currently being evaluated in a Phase III program, in approximately 105 patients being enrolled at multiple sites. The program consists of a three-month Phase III randomized, double-blind, placebo-controlled, parallel group study (also called C601 or DESTINY PWS) as well as a 12-month open-label safety extension study, which has recently been amended to allow patients the option to continue taking DCCR for an additional two years. All patients who complete the Phase III study are eligible to enroll into the open-label extension study (C602).

The Company continues to enroll patients into its ongoing DESTINY PWS study, which commenced in May 2018 and is evaluating DCCR tablets for the treatment of PWS. As of July 25, 2019, approximately 50% of the targeted number of patients have been enrolled into the DESTINY PWS clinical study and approximately 90% of them have either successfully completed or continue to be treated in the study. Approximately 90% of those completing the Destiny PWS study have elected to continue in C602, Soleno's open-label safety extension study and approximately 90% of those enrolled have continued to receive DCCR treatment in C602.

As of September 30, 2019, 19 trial sites have been activated in the U.S., and 7 sites have been activated in the United Kingdom. The most recent sites activated are Indiana University in Indianapolis, IN and St. Joseph's University Medical Center in Patterson, NJ in the U.S., and Fulbourn Hospital in Cambridge, Aintree University Hospital in Liverpool, Hammersmith Hospital in London, and The Royal Hospital for Sick Children in Glasgow in the U.K. Top-line data from the DESTINY PWS study is expected in the first half of 2020.

On March 14, 2019, and again on October 1, 2019, the Data Safety Monitoring Board, the independent group of experts monitoring the safety of the DESTINY PWS study, recommended the continuation of the study without modification, which supports the Company's understanding of DCCR's safety.

Item 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 13, 2019

SOLENO THERAPEUTICS, INC.

By: /s/ Jonathan Wolter
Jonathan Wolter
Chief Financial Officer
(authorized officer and principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Anish Bhatnagar, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2019

/s/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Jonathan Wolter, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2019

/s/ Jonathan Wolter
Jonathan Wolter
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2019

/s/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), Jonathan Wolter, Chief Financial Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2019

/s/ Jonathan Wolter
Jonathan Wolter
Chief Financial Officer
(principal financial and accounting officer)